Daniel Lutz (*Pro Hac Vice* pending)
Carter Dillard (State Bar No. 206276)
ANIMAL LEGAL DEFENSE FUND
170 E. Cotati Avenue
Cotati, CA 94931
Tel.: 707.795.2533
Emails: cdillard@aldf.org
dlutz@aldf.org

Paige M. Tomaselli (State Bar No. 237737)
CENTER FOR FOOD SAFETY
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
Tel.: (415) 826-2770 / F: (415) 826-0507
Email: ptomaselli@centerforfoodsafety.org

Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MEJ

ANIMAL LEGAL DEFENSE FUND, a non-profit corporation; and CENTER FOR FOOD SAFETY, a non-profit corporation,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant.

Case No. CV 13 4622

Assigned to:

Referred to:

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

FILED BY FAX

PRELIMINARY STATEMENT

1. The Animal Legal Defense Fund ("ALDF") and Center for Food Safety ("CFS") bring this action for injunctive and declaratory relief under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, to compel the United States Food and Drug Administration ("FDA") to cure the inadequate release and improper withholding of requested records.

2. In August 2012, ALDF requested FDA records related to the psychological, physiological, and behavioral effects of the animal drug ractopamine on humans and non-human animals. During the eight-month period following ALDF's request, FDA offered repeated promises of forthcoming documents yet provided no estimated decision dates and has ultimately produced nothing.

3. In March 2013, ALDF filed an administrative appeal of FDA's non-production of documents, and after lengthy delay, FDA produced a meager amount of records – less than one half of one percent of the responsive documents the agency says it has collected – that were the *exact* same compilation of records produced for a reporter in 2011.

4. One month after its inadequate response to ALDF's administrative appeal, FDA told ALDF that the agency is "in the process of securing additional staff to address the many requests in our backlog, including [ALDF's] request," indicating further agency delay.

5. ALDF is entitled to prompt release of records, and the Court should grant injunctive and declaratory relief accordingly.

6. In February 2013, CFS requested FDA records related to the environmental, human, and animal health effects of ractopamine. In the eight months since CFS submitted its request, CFS has received responses from three divisions within FDA, but an additional division with responsive records has offered repeated promises of forthcoming documents, yet provided no estimated decision date and has ultimately produced nothing.

7. In March and April 2013, CFS filed administrative appeals as to two divisions' responses. To date, CFS has not received any responses to its appeals.

8. CFS is entitled to prompt release of records, and the Court should grant injunctive and declaratory relief accordingly.

PARTIES

9. Plaintiff ANIMAL LEGAL DEFENSE FUND is a national non-profit organization of attorneys and more than 110,000 members and supporters incorporated in California and headquartered in Sonoma County. ALDF has a mission of working within the legal system to protect the lives and advance the interests of animals, including animals used in food production. ALDF regularly seeks and uses public records to support its mission.

10. Plaintiff CENTER FOR FOOD SAFETY is a national non-profit organization incorporated in Washington, D.C., with offices in Washington, D.C.; Portland, Oregon; and San Francisco, California. CFS has nearly 300,000 members who reside in every state across the country. A cornerstone of CFS's mission is to inform, educate, and counsel its members and the public on the harm done to human health, animal welfare, and the environment by industrial agriculture, including the use of beta-antagonist drugs such as ractopamine in food animal production. To support its mission, CFS regularly seeks, uses, and distributes public records.

11. Defendant UNITED STATES FOOD AND DRUG ADMINISTRATION is a federal agency within the United States Department of Health and Human Services. FDA qualifies as an agency under 5 U.S.C. § 552(f) and must comply with FOIA requests. FDA is headquartered in Silver Spring, Maryland.

JURISDICTION

12. This Court has subject-matter jurisdiction over the action because it arises under a federal statute and a United States agency is the defendant. 5 U.S.C. § 552(a)(4)(B); 28 U.S.C. §§ 1331, 1346.

13. This Court has personal jurisdiction over the parties, and venue in this Court is proper, because Plaintiff ALDF is headquartered and has a principal place of business in Sonoma County, in the Northern District of California. 5 U.S.C. § 552(a)(4)(B); 28 U.S.C. § 1391(e).

14. This Court has the authority to award costs and attorneys' fees under 28 U.S.C. § 2414 and 5 U.S.C. § 552(a)(4)(E).

INTRADISTRICT ASSIGNMENT

15. Assignment to the San Francisco Division is appropriate because ALDF made its FOIA request and received the inadequate FDA records at ALDF headquarters in Sonoma County, California. CFS made its FOIA request from its office in San Francisco, California. A substantial part of the events giving rise to this action took place in Sonoma and San Francisco Counties. *See* Civil L.R. 3-2(c), (d).

LEGAL FRAMEWORK

Freedom of Information Act

16. The Freedom of Information Act ("FOIA") promotes open government by providing every person with a right to request and receive federal agency records. 5 U.S.C. § 552(a)(3)(A), (f).

17. Agencies may promulgate rules stating the time, place, fees, and procedures to be followed in making FOIA requests. 5 U.S.C. § 552(a)(3)(A). FOIA procedures for FDA are codified at 21 C.F.R. §§ 20.1–20.120 (1999). Coextensive FOIA procedures for the Department of Health and Human Services, of which FDA is a subdivision, are codified at 45 C.F.R. §§ 5.1–5.69 (1997).

18. In furtherance of its design to encourage open government, FOIA imposes strict deadlines on agencies to provide responsive documents to FOIA requests. 5 U.S.C. § 552(a)(6)(A).

19. An agency must comply with a FOIA request by issuing a determination within twenty days after receipt of the request. An agency must immediately notify the requester of the determination and the reasons for it, and of the right of such person to appeal an adverse determination. 5 U.S.C. § 552(a)(6)(A)(i).

20. The agency has twenty days to make a determination with respect to any appeal. 5 U.S.C. § 552(a)(6)(A)(ii).

21. When an agency adopts a FOIA-processing system that creates a net effect of significantly impairing the requester's ability to obtain records or significantly increasing the amount of waiting time to obtain records, the agency's actions constitute improper withholding. *See McGehee v. CIA*, 697 F.2d 1095, 1110 (D.C. Cir. 1983). Courts have held that an

eight-month delay following a request with "[no] further information regarding the timeline for processing [the request] . . . . cannot be described as a model of due diligence." *Gov't Accountability Proj. v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp. 2d 55, 64 (D.D.C. 2008). Failing to provide an estimated decision date can itself be a violation of FOIA. 5 U.S.C. § 552(a)(7)(B)(ii); *Muttitt v. U.S. Cent. Command*, 813 F. Supp. 2d 221, 230-231 (D.D.C. 2011).

22. An agency's failure to comply with any timing requirements is deemed constructive denial and satisfies the requester's requirement to exhaust administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

23. Upon filing an administrative appeal, a requester satisfies the requirement of securing full administrative review before filing a lawsuit because "there [are] no further steps [the requester] could have taken in the administrative process." *See Kenney v. U.S. Dep't of Justice*, 700 F. Supp. 2d 111, 116-17 (D.D.C. 2010).

24. A FOIA requester who exhausts administrative remedies may petition the court for injunctive and declaratory relief from the agency's continued withholding of public records. 5 U.S.C. § 552(a)(4)(B); *e.g., Oregon Natural Desert Ass'n v. Locke*, 572 F.3d 610, 612-14 (9th Cir. 2009).

25. In addition, "it is well established that administrative exhaustion is not required where it would be futile because of certainty of an adverse decision." *Armstrong v. Bush*, 807 F. Supp. 816, 819 (D.D.C. 1992).

Federal Food, Drug, and Cosmetic Act

26. The Federal Food, Drug, and Cosmetic Act ("FFDCA") and its accompanying regulations govern the use of all new animal drugs. *See* 21 U.S.C. § 360b (2008). The purpose of the FFDCA is to protect consumer and animal health and safety.

27. The FFDCA requires the agency to refuse approval of an application for a new animal drug if there are no "adequate tests by all methods reasonably applicable to show whether nor not such drug is safe for use" or "the results of such tests show that such drug is unsafe for use." 21 U.S.C. § 360b(d)(1)(A)-(B).

28. In an application for agency approval of a new animal drug, a person must submit a significant number of records to FDA, including, *inter alia*, "full reports of investigations which have been made to show whether or not such drug is safe and effective for use"; "a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use"; and "the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe." *Id.* § 360b(b)(1)(A), (G), (H).

29. The revocation of new animal drug application approvals also turns on "whether such drug is safe for use." In determining whether a new animal drug is safe for use, the agency "shall consider . . . the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance." *Id.* § 360b(d)(2)(B).

30. The Center for Veterinary Medicine ("CVM"), as an office within FDA, regulates the manufacture and distribution of food additives and drugs that will be given to animals.

FACTS

FDA's Approvals of Ractopamine and its Applications

31. Ractopamine is a beta-agonist drug that induces increased heartbeat, relaxation of blood vessels, smooth muscle relaxation, and contraction of cardiac tissue in animals. It is widely used in U.S. meat production, primarily because the drug enhances lean muscle animal growth by inhibiting fat growth, stimulating lipolysis, increasing protein synthesis, and reducing protein breakdown in muscle. Ractopamine is linked to significant health problems in animals, such as cardiovascular stress, muscular skeletal tremors, "downer" animals, hoof lesions increased aggression, and hyperactivity.

32. FDA first approved the use of ractopamine as a new animal drug in 2000, for use in pigs. *See* New Animal Drugs for Use in Animal Feeds; Ractopamine Hydrochloride, 65 Fed. Reg. 4111-01 (Jan. 26, 2000).

33. The agency subsequently approved new applications of ractopamine numerous

times between 2001 and 2010. *See, e.g.,* 66 Fed. Reg. 21283-02 (Apr. 30, 2001) (ractopamine and tylosin, marketed as "Paylean" for pigs); 67 Fed. Reg. 71820-01 (Dec. 3, 2002) (supplemental drug marketed as "Paylean" and "Tylan" combination for pigs); 68 Fed. Reg. 54658-02 (Sept. 18, 2003) (ractopamine marketed as "Optaflexx" for cattle); 69 Fed. Reg. 12067-02 (Mar. 15, 2004) (ractopamine, monensin, and tylosin combinations for cattle); 71 Fed. Reg. 31073-02 (Jun. 1, 2006) (four-way combination of ractopamine and other drugs for heifers); 73 Fed. Reg. 72714-01 (Dec. 1, 2008) (ractopamine marketed as "Topmax 9" for turkeys).

34. FDA promulgated a regulation requiring cautionary labeling in 2002. 67 Fed. Reg. 47691-01 (Jul. 22, 2002) ("Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome . . . . Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean."). Four years later, the agency removed its regulation's references to "downer" pigs. 71 Fed. Reg. 67300-01 (Nov. 21, 2006) (changing language to, "Ractopamine may increase the number of injured and/or fatigued pigs during marketing.").

35. As part of FDA's approval and regulation of new animal drug applications, the agency sets "tolerance levels" for residues remaining in the meat produced by the slaughter of the drug-fed target animal. *See, e.g.*, 21 C.F.R. § 556.570 (2008).

36. In July 2012, the United Nations international food standards body Codex Alimentarius Commission adopted "maximum residue limits" (*i.e.*, tolerance levels) for ractopamine. The internationally adopted levels are more stringent than FDA standards.

37. Many foreign jurisdictions, including the European Union, China, and Russia, ban the importation of meat that contains any ractopamine residue.

38. On August 7, 2013, Tyson, Inc. announced that on September 6, 2013, it would no longer accept cattle fed the animal drug Zilmax. Like ractopamine, Zilmax is in the class of drugs known as beta-agonists, and has been linked to target animals becoming reluctant to move, walking gingerly, and showing signs of lameness. The following week, Zilmax manufacturer Merck Animal Health announced that it would temporarily suspend sales of the

drug, stating that the suspension "will allow sufficient time for the establishment of valid study protocols, identification of feeders and packers to participate in the audit, and creation of a third-party team to oversee this process and validate its results."

The ALDF FOIA Records Request to FDA

39. ALDF requested records from FDA on August 31, 2012, seeking information related to the animal drug ractopamine. The request specifically asked for:

- All Food and Drug Administration records documenting, analyzing, or otherwise discussing the physiological, psychological, and/or behavioral effects of Ractopamine on pigs, cattle, turkeys and humans, *including but not limited to* documentation concerning the effects of Ractopamine on target animal or human liver form and function, kidney form and function, thyroid form and function, urethral form and function, prostate form and function, tumor development, behavioral aggression, lameness, hyperactivity, stiffness, trembling, dyspnea, hoof disorder, collapse, recumbency, reluctance to move, or death.
- All Food and Drug Administration records documenting, analyzing, or otherwise discussing evidence of the physiological, psychological and/or behavioral effects of Ractopamine on pigs, cattle, turkeys and humans, *including but not limited to* those effects described in the above bullet point, that led the Food and Drug Administration to approve the new animal drug applications for Ractopamine (including Optaflexx, Paylean, and Topmax).
- All Food and Drug Administration records documenting, analyzing, or otherwise discussing the physiological, psychological, and/or behavioral effects of Ractopamine on pigs, cattle, turkeys and humans, *including but not limited to* those effects described in the first bullet point, following the approval of Ractopamine.

40. FDA did not respond within twenty days after the August 31, 2012 request.

41. On October 25, 2012, Peter Jaensch, regulatory counsel for FDA's Office of

New Animal Drug Evaluation, wrote to ALDF for clarification on the scope of the FOIA request. ALDF responded the following day.

42. On December 31, 2012, after two more months of agency silence, ALDF contacted Mr. Jaensch to ask if ALDF had adequately clarified the scope of request. In this correspondence, ALDF also requested that FDA provide records on a rolling basis.

43. On January 2, 2013, Mr. Jaensch responded that ALDF's October correspondence did clarify the scope, that he would forward ALDF's preference for a rolling release to the appropriate FDA FOIA officer, and that "the search for collection of responsive documents is underway."

44. On February 7, 2013, following another month of silence, ALDF attempted to call and emailed Frederick Sadler, Director of FDA's Division of Freedom of Information Office, to ask about the agency's lack of response in producing records. Mr. Sadler responded that an official from CVM would respond to ALDF.

45. No one contacted ALDF for another month.

46. On March 5, 2013, ALDF initiated an administrative appeal regarding FDA's delay in producing records. Various staffers from the FDA Freedom of Information Office, as well as CVM, responded to ALDF with emails indicating that a search was underway. This response did not include any dates indicating when a partial or total record release would occur.

47. Laura Bradbard, Director of Communications for CVM, emailed ALDF on March 11, 2013, to explain the agency's FOIA processing. Ms. Bradbard stated that the agency "identified and scanned all responsive documents in preparation for redacting any non-releasable information and at this point have more than 100,000 pages to review."

48. FDA did not provide any documents for another two months.

49. In early May, a new FOIA Officer for CVM, Gorka Garcia-Malene, called ALDF. He explained that the agency has a "first-in, first-out" policy, and that the requested records were forthcoming. FDA still did not set specific dates for partial or complete record release.

50. FDA produced its first set of records on May 8, 2013, more than eight months

after ALDF's initial request. The first set of documents comprised 464 pages, less than one half of one percent of the 100,000 pages that FDA told ALDF it collected and scanned.

51. Although FDA claimed to be searching, scanning, and redacting requested records over many months, the 464 pages of records are *the exact same* 464 pages of records released to a Food Safety News reporter in 2011, down to the CVM "Search Criteria Cover Sheet," dated April 18, 2011.

52. In the only instance of FDA's acting with haste on ALDF's request, the agency immediately followed the 464-page release with a May 13, 2013, letter to ALDF closing the administrative appeal file.

53. After yet another month of agency silence, ALDF asked Mr. Garcia-Malene for an update on the records production process. Mr. Garcia-Malene responded on June 3, 2013, that the agency is "in the process of securing additional staff to address the many requests in [its] backlog, including [the ALDF request]." He gave no estimated date of the next release or when the process would be completed.

54. On August 5, 2013, Plaintiffs met with FDA to discuss both organizations' long-standing FOIA requests for records related to ractopamine. The only FOIA-related outcome of the meeting was that FDA identified Mr. Garcia-Malene as the formal "FOIA Liaison" for both organizations' records requests.

55. On August 15, 2013, Plaintiffs and FDA held a conference call to discuss the records requests. Mr. Garcia-Malene again generally repeated that the records ALDF requested are forthcoming, but did not specify a timeline, despite Plaintiffs' specific request for FDA to estimate upcoming release dates.

56. Since August 15, 2013, neither Mr. Garcia-Malene nor anyone else at FDA has contacted ALDF with regard to the August 31, 2012, records request.

57. Plaintiff ALDF has fully exhausted its administrative remedies. Administrative remedies are deemed exhausted whenever an agency fails to comply with the applicable time limits, as stated by 5 U.S.C. § 552(a)(6)(C). Plaintiff now turns to this Court to enforce the public access to agency records and other remedies guaranteed by FOIA.

The CFS FOIA Records Request to FDA

58. On February 4, 2013, CFS submitted a FOIA request to FDA seeking information related to the animal drug ractopamine. Specifically, CFS requested:

- Any and all documents relating to environmental effects or safety of ractopamine, also marketed as Optaflexx, Paylean, and Topmax (collectively hereinafter "ractopamine), including but not limited to environmental assessments, findings of no significant impact, and other documents related to National Environmental Policy Act (NEPA) compliance.

- Any and all documents pertaining to FDA communications with Environmental Protection Agency (EPA) concerning ractopamine, including any documents concerning potential environmental, animal health, or human health issues associated with use of ractopamine in food-producing animal feed.

- Any and all documents concerning reports of any adverse reactions or adverse events for ractopamine, including but not limited to the reports, studies and other information pertaining to safety and effectiveness of new animal drugs required to be submitted to FDA by 21 C.F.R. § 514.80.

- Any and all FDA warning letters concerning ractopamine.

- Any and all documents concerning tolerance levels for ractopamine.

- Any and all documents concerning withdrawal periods for ractopamine.

- Any and all documents concerning acceptable daily intake for ractopamine.

- Any and all documents concerning the labeling of ractopamine.

- Any and all documents concerning toxicity of ractopamine.

- Any and all documents concerning communications or meetings with industry (including but not limited to the pharmaceutical, agriculture or food industries) or trade groups (including but not limited to pharmaceutical, agriculture or food trade groups) about ractopamine.

- Any and all documents concerning communications or meetings with the Codex Committee on Residues of Veterinary Drugs in Foods (the "Committee") or any member of the Committee, including but not limited to the Committee's 2008 expert report, regarding ractopamine.

- Any and all documents concerning complaints or comments from

members of the public concerning ractopamine.

- Any and all documents concerning FDA's ability to collect fees for certain animal drug applications, and for the establishments, products and sponsors associated with these and previously approved animal drug applications, in support of the review of animal drugs under the Animal Drug User Fee Act of 2003 (21 U.S.C. s. 379j-11 and j-12) for ractopamine.

- Any and all documents concerning FDA's testing of meat products for ractopamine, including but not limited to the methods used, how frequently it is performed, and test results.

- Any and all documents concerning FDA communications with the Office of the U.S. Trade Representative regarding ractopamine.

59. On February 13, 2013, CFS received a partial response from FDA's Division of Dockets Management ("DDM").

60. On March 5, 2013, CFS received a partial response from FDA's Office of Executive Secretariat ("OES"). The response also stated:

> You have the right to appeal this response. If you dispute FDA's preliminary determination, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

61. On April 4, 2013, CFS filed an administrative appeal of OES's response on the bases that OES (1) failed to conduct a reasonably adequate search for records responsive to CFS's FOIA request and (2) improperly redacted certain records.

62. FDA did not make a determination within twenty days. To date, the agency has not made a determination on this appeal.

63. On April 2, 2013, CFS received a partial response from FDA's Office of Chief Counsel ("OCC"). The response also stated:

> If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with

> respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision.

64. On May 2, 2013, CFS filed an administrative appeal of OCC's response on the bases that OCC (1) does not have authority to request an "interim" administrative appeal and to make such appeal due within 30 days, (2) improperly redacted certain records, (3) failed to conduct a reasonably adequate search for responsive records, and (4) failed to respond within the statutorily-mandated timeframe under FOIA.

65. FDA did not make a determination within twenty days. To date, the agency has not made a determination on this appeal.

66. On April 4 and 5, 2013, FDA confirmed by email that CFS's FOIA request was still pending, "as CVM has not yet responded." To date, CFS has not received a response from CVM.

67. On July 10, 2013, CVM contacted CFS to clarify its request, which CFS did by email on the same date. Although CFS asked, CVM would not provide an anticipated production date.

68. On August 5, 2013, Plaintiffs met with FDA to discuss both organizations' long-standing FOIA requests for records related to ractopamine. The only FOIA-related outcome of the meeting was that FDA identified Mr. Garcia-Malene as the formal "FOIA Liaison" for both Plaintiffs' records requests.

69. On August 15, 2013, Olivia Booth from FDA's Program Support Center contacted CFS and stated, "[w]e are currently reviewing your appeal and noticed that you have been in contact with the FDA about proceeding with a minor deletions case instead of an appeal with our office. Feel free to call me at any time to discuss whether or not you would like us to continue processing your appeal." Although Ms. Booth referenced "FOIA appeal #13-0311," to CFS's knowledge neither of its appeals had been assigned a tracking number. CFS's attempts to clarify to which request the email pertained went unanswered, and thus it is still unclear to Plaintiff whether this correspondence pertains to its appeal to OES or OCC. CFS responded that "our current Administrative Appeal should be stayed for the time being until all FDA

divisions respond and the Administrative Appeal process formally begins."

70. Also on August 15, 2013, Plaintiffs and FDA held a conference call to discuss the records requests. CFS clarified the scope of its request during the call and further by emails on September 3 and 19, 2013. Despite CFS's specific request for an estimated response date on September 19, 2013, FDA still would not set specific dates for partial or complete records release or an estimated decision date, explaining only that CVM "will process this request as soon as we can."

71. Since August 15, 2013, neither CVM nor any other division within FDA has provided any records to CFS, nor an estimated decision date or response date.

72. Plaintiff CFS has fully exhausted its administrative remedies. Administrative remedies are deemed exhausted whenever an agency fails to comply with the applicable time limits, as stated by 5 U.S.C. § 552(a)(6)(C). Plaintiff now turns to this Court to enforce the remedies and public access to agency records guaranteed by FOIA.

FIRST CAUSE OF ACTION

Violation of Freedom of Information Act Based on ALDF FOIA Request No. 2012-6491

73. The allegations in the preceding paragraphs are re-alleged and incorporated by reference as if fully set forth herein.

74. ALDF made a proper FOIA request for information relating to the animal drug ractopamine. 5 U.S.C. § 552(a)(3)(A).

75. FDA has since unlawfully withheld the requested information from ALDF by failing to provide it within the statutory deadlines.

76. FDA has also failed to satisfy its January 2, 2013, agreement with ALDF to provide records on a rolling basis. Since that date, it has only provided ALDF with one set of responsive records that were already prepared for another requester in 2011. FDA has not set any dates for future rolling records releases, nor has it set a date to finish its complete release of responsive records.

77. FDA's failure to communicate with ALDF about the status of the FOIA request,

coupled with its failure to set or observe deadlines, constitutes a lack of due diligence and a violation of FOIA.

78. ALDF exhausted administrative remedies by appealing FDA's unlawful delay and withholding of the requested information on March 5. FDA denied ALDF's appeal by first delaying response, then releasing inadequate records, and finally closing the ALDF appeal file.

79. FDA has also constructively denied ALDF's request for information by failing to adhere to the time limits prescribed by 5 U.S.C. § 552(a)(6)(A).

80. ALDF has suffered irreparable injury and has no relief at law, leaving only equitable remedies of injunctive and declaratory relief.

81. Accordingly, ALDF has a right under FOIA to injunctive and declaratory relief against FDA for the agency's unlawful withholding of information.

SECOND CAUSE OF ACTION

Violation of the Freedom of Information Act Based on CFS FOIA Request No. 2013-923

82. The allegations in the preceding paragraphs are re-alleged and incorporated by reference as if fully set forth herein.

83. CFS made a proper FOIA request for information relating to the animal drug ractopamine. 5 U.S.C. § 552(a)(3)(A).

84. FDA has since unlawfully withheld the requested information from CFS by failing to provide it within the statutory deadlines.

85. FDA has also failed to set any dates for future sets of record releases, nor has it set a date to finish its complete release of responsive records.

86. FDA's failure to communicate with CFS about the status of the FOIA request, coupled with its failure to set or observe deadlines, constitutes a lack of due diligence and a violation of FOIA.

87. CFS exhausted administrative remedies by appealing FDA's unlawful delay and withholding of the requested information on March 2 and April 4. FDA has constructively denied CFS's appeals by failing to make a determination within statutory deadlines.

88. FDA has also constructively denied CFS's request for information by failing to

adhere to the time limits prescribed by 5 U.S.C. § 552(a)(6)(A).

89. CFS has suffered irreparable injury and has no relief at law, leaving only equitable remedies of injunctive and declaratory relief.

90. Accordingly, CFS has a right under FOIA to injunctive and declaratory relief against FDA for the agency's unlawful withholding of information.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

1. Order FDA to expeditiously produce all records requested by Plaintiffs;

2. Declare as unlawful FDA's failure to respond to Plaintiffs' FOIA requests;

3. Declare as unlawful FDA's failure to disclose records that Plaintiffs have requested;

4. Declare as unlawful FDA's inadequate searching and improper withholding of documents, by failing to disclose any requested records with respect to ALDF's request except the 464 pages that FDA previously released to a reporter in 2011;

5. Declare as unlawful FDA's failure to provide any estimated response or decision dates;

6. Exercise close supervision over FDA as it processes Plaintiffs' requests;

7. Award to Plaintiffs all costs and reasonable attorneys' fees as provided in 5 U.S.C. § 552(a)(4)(E) or any other law; and

8. Grant other and further relief as the Court may deem just and proper.

Dated: October 7, 2013

Respectfully submitted,

/s/ Daniel Lutz

Daniel Lutz (*Pro Hac Vice pending*)

/s/ Carter Dillard

Carter Dillard (State Bar No. 206276)
ANIMAL LEGAL DEFENSE FUND
170 E. Cotati Avenue
Cotati, CA 94931
Tel.: (707) 795-2533
Emails: dlutz@aldf.org
cdillard@aldf.org

Counsel for Plaintiff ALDF

Paige M. Tomaselli (State Bar No. 237737)
CENTER FOR FOOD SAFETY
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
Tel.: (415) 826-2770
Email: ptomaselli@centerforfoodsafety.org

Counsel for Plaintiff CFS